America's Blood Centers

OUR MEMBERS SERVE COMMUNITIES NATIONWIDE

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December 22, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

RE: Docket No. 98N-0581: Requirements for Testing Human Blood for Evidence of Infection Due to Communicable Disease Agents

Dear Dockets Management Staff:

America's Blood Centers (ABC) is pleased to comment on the Food and Drug Administration's Proposed Rule: Requirements for Testing Human Blood for Evidence of Infection Due to Communicable Disease Agents.

We support FDA's stated goal of helping blood establishments protect the safety of the blood supply and establishing policies with the intent of promoting consistency in the industry. We seek clarification and offer requested input in the following areas:

Testing of Autologous Donations.

We support the concept of testing of autologous donations. As FDA observes, error and accident reports indicate that the inadvertent transfusion of such units into the incorrect recipient occurs. However, we urge FDA to consider flexibility in regard to such testing.

To what extent does FDA propose such testing? Proposed section 610.40 would require "uniform testing for both autologous and allogeneic donation." Currently allogeneic donations are being tested under various IND protocols with nucleic acid testing (NAT). NAT is not allowed on autologous units under the existing INDs, and whether NAT should be required for autologous units if and when a platform is licensed needs public consideration.

In many cases, multiple autologous units are donated in a short time. Mandatory testing of each and every unit would not contribute to safety, would be expensive, and could delay availability.

We support mandatory testing of only one of the series of autologous units especially where the donor has a known disease marker.

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To what extent should autologous units be submitted for confirmatory testing? Many blood establishments currently submit one of the series of autologous donations for confirmatory testing; as iterated above, requiring each and every unit to have such confirmatory testing will not contribute to safety, will be expensive, and will delay the availability of autologous components.

We support mandatory confirmatory testing of only one of the series of autologous units when a screening test on one or more of the series is repeatedly reactive.

Further Testing

We support the proposed requirement that reactive samples be further tested by a supplemental (additional, more specific) test.

We encourage the agency to consider the use of a reactive NAT test, as defined by the applicable IND, to be acceptable to confirm infection, resulting in the donor's permanent deferral.

Requiring a reactive screening test to be further confirmed by supplemental testing in addition to a positive NAT result will add to the cost and turn-around-time to complete testing and does not make full use of the power of Nucleic Acid testing. Physicians of donors referred for clinical follow up based on confirmation by an unlicensed NAT assay can be given the message that the confirmatory assay is unlicensed. Medical judgement can be used by the clinician regarding further testing.

Restrictions on Shipping Positive Units

We find it curious that FDA specifically exempts autologous units from the restrictions prohibiting shipping of units confirmed to be test positive for a communicable disease. We agree that units shown to be of low risk (positive anti-HBc, RPR, false positive HIV, false positive HCV, non-neutralizable HBsAg) units should certainly be shipped and be made available for transfusion to the autologous donor. However, there is great concern about whether confirmed positive HIV, HBV and HCV units should be treated in the same manner.

If FDA's rationale for requiring testing of autologous blood is in response to reports of errors in transfusing such blood to the incorrect patient, then providing known infectious units to hospital transfusion services does not prevent such errors and defeats the stated purpose of testing. Even obvious labeling of such units as described in the proposed rule will not entirely prevent errors and accidents. We are aware that a proscription against distribution of such autologous units may conflict with judicial precedent regarding the American's with Disabilities Act, but still question the wisdom of allowing transfusion services to enter known infectious components into their inventories.

Additional Comments

- We support the **elimination of testing for syphilis** as a marker of high-risk behavior, as a surrogate test for other infectious diseases, and in preventing the transmission of syphilis through blood transfusion. In addition, recent epidemiologic data published by CDC demonstrate that rates of primary and secondary syphilis are at historic lows and, therefore, with the falling positive predictive value of a reactive serologic test for syphilis, any historic utility is eroded by its persisting nonspecificity.

- We support the proposed initiatives regarding the **release of untested or incompletely tested blood in medical emergencies** and routine shipment of specific blood components for further manufacture prior to completing of testing to insure the timely production of such biologicals as interferon.

- We support maintaining flexibility by **allowing testing to be completed only once at the beginning of a 30-day period of donation by a dedicated apheresis donor for a single recipient**.

- We support the proposed requirement that **all testing laboratories be CLIA approved and registered with FDA**.

- We support the proposal to **exempt source plasma from HTLV testing.**

- We support the proposed exemption to allow the **use of recovered plasma from blood that is repeatedly reactive for anti-HBc and negative for HbsAg for further manufacture** into plasma derivatives and the exemption of source plasma for manufacture into plasma derivatives from being tested for anti-HBc.

Once again, thank you for the opportunity to comment. If you would like to discuss the above questions further, I can be reached at (806) 358-4563.

Yours truly,

Mary Townsend (JS)

Mary Townsend, MD, Chair
Scientific, Medical and Technical Committee
America's Blood Centers